## THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 33

#### UNITED STATES PATENT AND TRADEMARK OFFICE

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# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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Ex parte ARIE BEN-BASSAT,
ROBERT BRUNER,
SHARON SHOEMARKER,
YEHOSHUA ALONI, HARRY WONG,
DONALD C. JOHNSON
and AMAR N. NEOGI

\_\_\_\_\_

Application 08/069,458

ON BRIEF

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Before WILLIAM F. SMITH, SPIEGEL, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

## **DECISION ON APPEAL**

This is an appeal under 35 U.S.C. 134 from the final rejection of claims 49-55.

Claims 49 and 55 are representative of the subject matter on appeal and read as follows: A biologically pure strain of <u>Acetobacter</u> and progeny thereof, characterized as being capable of producing substantially pure reticulated cellulose and by production of substantially low amounts of gluconic acid and ketogluconic acids in glucose-containing medium as determined in samples by observing a low frequency of calcuim carbonate clearing colonies on 1% calcium carbonate agar plates containing glucose.

A mutant strain of <u>Acetobacter</u> microorganism selected from the group consisting of strains ATCC Nos. 53264, 53263 and 53524.

The references relied upon by the examiner are:

Ring et al. (Ring)	4,588,400	May 13, 1986	
Ben-Bassat et al. (>162)	5,079,162	Jan.	7, 1992 (filed Dec. 16, 1982)
Kusakabe et. al. (Kusakabe) (British Patent)	1,570,487	July	2, 1980

Ramamurti et al. (Ramamurti), "Cellulose Formation by *Acetobacter acetigenum* in a 50% (w/v) Glycerol Synthetic Medium," *Biotechnology and Bioengineering*, Vol. XXIV, 2267-2268 (John Wiley & Sons, Inc. 1982).

Valla, et al. (Valla), "Cellulose-negative Mutants of *Acetobacter xylinum*," 128 *Journal of General Microbiology* 1401-1408 (1982).

## **GROUNDS OF REJECTION ON APPEAL**

- Claims 49-54 stand rejected under 35 U.S.C. 112, first paragraph, as being based on an insufficient disclosure to support or enable the scope of the claims currently claimed.
- Claim 55 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of >162.
- Claims 49-55 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35

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U.S.C. 103 as obvious over Ring or Valla or Kusakabe or Ramamurti.

We reverse the rejection under 35 U.S.C. ¹ 112, first paragraph, vacate the obviousness-type double patenting rejection in view of a new ground of rejection under 37 C.F.R. ¹ 1.196(b) and remand this application to the examiner for reevaluation of the 102(b)/103 rejection.

#### **DISCUSSION**

In reaching our decision in this appeal, we have given careful consideration to the appellants= specification and claims, and to the respective positions articulated by the appellants and the examiner. We make reference to the Examiner's Answer (Paper No. 22, mailed October 4, 1994), and the Supplemental Examiner's Answer (Paper No. 26, mailed March 6, 1995) for the examiner's reasoning in support of the rejection. We further reference appellants=Brief¹ (Paper No. 21, filed May 2, 1994), and appellants=Reply Brief (Paper No. 23, filed December 1, 1994) for the appellants=arguments in favor of patentability.

# The rejection under 35 U.S.C. 112, first paragraph:

At page 3 of the Examiner Answer, the examiner states Ano example or description is provided as to any mutagenic process which would yield such a strain [capable of producing \*substantially=pure cellulose under \*substantially=continuous agitation] . . .. Further the specification provides no guidance as to how to identify, isolate or obtain a bacteria which fits the description. At page 4 of their Reply Brief, appellants point to Examples 3 and 4 stating the specification Adescribes methods of mutagenizing and screening *Acetobacter* . . . for strains capable of producing reticulated cellulose in the claimed methods. The Supplemental Examiner Answer does not address this issue.

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<sup>&</sup>lt;sup>1</sup> We note that page 3 of Appendix B, attached to appellants=Brief makes reference to the 1985 ATCC Catalog. Appellants=state A[c]opies of pertinent sections of the 1985 catalog are attached hereto as Exhibit B.® Exhibit B was not present, as an attachment to Appendix B or among any of the Appendices attached to the Brief.

In addition to appellants=Reply Brief we recognize pages 22, 23 and 33-35 of the specification where *Acetobacter* strains are mutagenized and successfully screened for the claimed characteristics. Therefore, we disagree with the examiner's conclusion at page 3 of the Examiner's Answer that A[t]hus even if one skilled in the art ran the process, the artisan would be left to guess as to whether the microorganism would fit within the scope of the claims.®

The examiner takes the position, in the bridging paragraph of pages 8-9 of the Examiner's Answer that:

[T]he prior art (see the Valla reference) suggests different forms or mutants of <u>Acetobacter</u> which do not produce cellulose. Thus it is not readily predictable which strains of <u>Acetobacter</u> will perform in the claimed process and appellants have provided insufficient guidance to permit ready determination of those strains which will work and those strains which will not work in the absence of excess experimentation.

The examiner continues at page 9 of the Examiner's Answer with the statement A[a]lso spontaneously formed negative cellulose mutants of A. xylinum were found to accumulate if the wild type was grown and transferred repeatedly in shake flask cultures (see [Valla] page 1402 of the Results). At page 10 of the Examiner's Answer, the examiner states A[t]o select for the cellulose negative forms and the cellulose positive forms would be tedious and the stability of these types as demonstrated by the Valla reference would be unpredictable in this art.

In the bridging paragraph of pages 12-13 of the Examiner's Answer, the examiner states:

Thus, the undue practice of many techniques may be required to practice appellants=claimed invention especially since appellants admit that stability and low gluconic acid production are not necessarily required to produce reticulated cellulose (see page 23 lines 1-5, of the instant Appeal Brief) . . . . Agitation alone does not provide sufficient criterion for the production of reticulated cellulose since negative cellulose strains and mutants are produced under agitated conditions spontaneously and via the use of specific mutagens.

## In response, appellants states:

Appellants believe that this new argument by the examiner reveals a fundamental misunderstanding of the claimed invention. The claimed invention is not directed to using agitation as a method of mutagenesis. The claims are directed to strains of *Acetobacter* that are capable of producing reticulated cellulose under the appropriate conditions.

See, Reply Brief page 5.

We agree with appellants.

In considering the enablement rejection before us for review, we find the following passage from *PPG Indus.*, *Inc.* v. *Guardian Indus. Corp.*, 75 F.3d 1558, 1564 37 USPQ2d 1618, 1623 (Fed. Cir.

### 1996) relevant:

In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. *See, e.g., In re Goodman,* 11 F.3d 1046, 1050-52, 29 USPQ2d 2010, 2013-15 (Fed. Cir. 1993); *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d. 1200, 1212-14, 18 USPQ2d 1016, 1026-28 (Fed. Cir.), *cert. denied,* 502 U.S. 856 (1991); *In re Vaeck,* 947 F.2d at 496, 20 USPQ2d at 1445. Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation. But the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation Amust not be unduly extensive. *Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The Patent and Trademark Office Board of Appeals summarized the point well when it stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

Ex parte Jackson, 217 USPQ 804, 807 (1982).

The examiner takes the position that mutation of *Acetobacter* will result in cellulose positive strains that will revert to cellulose negative mutants upon further culture. *See*, Examiner's Answer, pages 10-11. To support this conclusion, the examiner relies upon Valla. However, upon review of the Valla reference, it appears that the conclusion reached therein is inconsistent with the examiner's position. Valla starts with cellulose positive strains of *Acetobacter xylinum*. Valla then observe that this cellulose positive strain of *Acetobacter xylinum* was capable of spontaneously (and reversibly) mutating to cellulose negative strains upon extended culture. Valla specifically state at page 1404 A[t]he apparent selection of CeI mutants by growth in shake flask culture is thus at least partly a consequence of the method of sampling, the CeI cells being transferred and the CeI<sup>†</sup> cells in the aggregates being left behind.

At page 1405, Valla conclude that A[t]he very high frequency of cellulose-negative mutants often observed during routine cultivation of the wild-type *A. xylinum* is thus due to biological selection [e.g. the CeI cells being transferred and the CeI<sup>†</sup> cells in the aggregates being left behind] and not to an extremely high mutation frequency.

With the specification disclosure of how to mutate and screen for a biologically pure strain of *Acetobacter* as claimed, and Valla deaching that cellulose negative mutants are due to biological selection, not an extremely high mutation frequency, there is no remaining factual basis to support the conclusion that the claims are not enabled by the specification. While a certain degree of experimentation may be necessary, what is required from the examiner is a fact-based explanation stating why such experimentation would be Aundue. We recommend that the examiner review *Enzo Biochem, Inc. v. Calgene, Inc.,* 188 F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999). Therein, the court provided a model analysis of enablement issues and illustrated the type of fact finding which is needed before one is in a proper position to determine whether a given claim is enabled or non-enabled.

The examiner states, in the bridging paragraph of pages 11-12 of the Examiners Answer, that Appellants have only provided working examples of specific strains and have not actually screened for any other strains to show that the amount of direction or guidance and quantity of experimentation necessary is sufficient to enable the claimed invention to the extent encompassed by the present claim scope. The examiner continues on page 12 of the Examiners answer that, A[i]t is not clear from the declarations, in support of this argument, that any and all mutants will produce reticulated cellulose; especially since Valla teaches that the two forms, that is cellulose producing and non-cellulose producing, vary considerably and that a mixture of these cells may coexist in culture.

The examiner's position appears to be that the claims include inoperative embodiments.

Therefore, the examiner is directed to *Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1576-77, 224 USPQ 409, 414 (Fed. Cir. 1984):

Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. AIt is not a function of the claims to specifically exclude . . . possible inoperative substances . . . . *In re Dinh-Nguyen*, 492 F.2d 856, 859-59, 181 USPQ 46, 48 (CCPA 1974)(emphasis omitted). *Accord, In re Geerdes*, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974); *In re Anderson*, 471 F.2d 1237, 1242, 176 USPQ 331, 334-35 (CCPA 1971). Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid. *See*, *e.g.*, *In re Cook*, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

The specification, of this application, discloses how to mutate and screen for a biologically pure strain of *Acetobacter* having the claimed characteristics. *See e.g.*, Specification, pages 28-37. In view of this, the examiner's analysis does not support the conclusion that the claims include a significant number of inoperative combinations that would require one of ordinary skill in the art to experiment unduly in order to practice the clamed invention.

Accordingly, we reverse the rejection of the claims under 35 U.S.C. 112, first paragraph.

Having determined that the examiner failed to meet her burden under 35 U.S.C. 1112, we find it unnecessary to discuss appellants=Declarations, relied upon by appellants to rebut the examiner's position.

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Claim 55 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of  $^{>}162$ .

Any analysis employed in an obviousness-type double patenting rejection must parallel the analysis used to determine obviousness under 35 U.S.C. 103.

At page 4 of the Examiner's Answer, the examiner states:

Although the conflicting claims are not identical, they are not patentably distinct from each other because the product of the patent does not patentably differ from the product claimed in claim 55, note the claims of the patent. Further, both the product of the patent and the product of claim 55 are produced by the same process wherein agitation is used in a fermentation process to form reticulated cellulose.

Note the examiner's statement, that A[f]urther, both the product . . . produced by the same process wherein agitation is used in a fermentation process to form reticulated cellulose. The claims of >162 are directed to biologically pure strains of *Acetobacter*. Appealed claim 55 is directed to a mutant strain of *Acetobacter*. Therefore, it is unclear why the examiner references a fermentation process to form reticulated cellulose. The examiner recognizes at page 14 of the Examiner's Answer, that A[a]ppellants argue that the strains of >162 are different from the claimed mutant strains since the claimed biologically [pure] strains of >162 are not the mutant(s) as claimed herein. However, the examiner maintained the rejection concluding, Athe claimed mutants appear to not differ significantly from the patented strains of >162. See, Examiner's Answer, page 14. Missing from the examiner's explanation is a factual analysis to support this conclusion.

In the bridging paragraph of pages 33-34 of appellants=Brief, appellants state:

In the Final Rejection mailed January 26, 1993 (07/683,304, Paper 10). Claim 55 was rejected under 35 U.S.C. ¹ 101 for double patenting and claiming the same invention as Claims 1 through 5 of U.S. Patent 5,079,162.... The [e]xaminer has stated that reasons for making the obviousness-type double patenting rejection are the same as her reasons for making the rejection under 35 U.S.C. ¹ 101, i.e., that she sees no difference between the claimed subject matter in claim 55 and the claims in U.S. Patent No. 5,079,162.

A double patenting rejection of the obvious type is Annalogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. ' 103@ except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 600 n.4, 154 USPQ 29, 34 n.4 (CCPA 1967). Therefore, any analysis employed in an obvious-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. ' 103 obviousness determination. *In re Braat*, 937 F.2d 589, 592-93, 19 USPQ2d 1289, 1292 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 892 n.4, 225 USPQ 645, 648 n.4 (Fed. Cir. 1985).

Because the examiner failed to analyze this obviousness-type double patenting rejection in a manner which parallels the guidelines for analysis of a 35 U.S.C. ' 103 obviousness determination, we vacate the examiner's rejection in view of a new ground of rejection under 37 C.F.R. ' 1.196(b).

# New ground of rejection under 37 C.F.R. 1.196(b):

Claim 55 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over (1) claims 1, 3 and 5, or in the alternative, over (2) claims 3-5 of >162. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claim 55 is drawn to a mutant strain of *Acetobacter* microorganism selected from the group consisting of strains ATCC Nos. 53264, 53263 and 53524. There are two possible interpretations of this claim:

The mutant strain is either ATCC No. 53264 [1306-3], 53263 [1306-11] or 53524 [1306-21] (as disclosed in the specification at pages 20-22 each of these strains is a mutant strain of *Acetobacter*); or

The mutant strain is a further mutant of either ATCC No. 53264 [1306-3], 53263 [1306-11] or 53524 [1306-21].

Appellants interpret the claim to read as alternative 2. At page 34 of the Brief, appellants=state, A[t]hese strains are different than the subject matter of >162 as they are mutants of the strains recited in Claims 1, 3 and 5 of the >162 patent.@

The claims of >162 read as follows:

Claim 1. A biologically pure strain of Acetobacter ATCC 53264.

Claim 2. A biologically pure strain of Acetobacter ATCC 53749.

Claim 3. A biologically pure strain of Acetobacter ATCC 53263.

Claim 4. A biologically pure strain of Acetobacter ATCC 53750.

Claim 5. A biologically pure strain of Acetobacter ATCC 53524.

It is clear from the instant specification that:

1306-11 [ATCC No. 53263] is a mutant of 1306-3 [ATCC No. 53264]. *See*, Examples III-IV, pages 32-33.

1306-21 [ATCC No. 53524] is a mutant of 1306-3 [ATCC No. 53264]. *See*, Example V, pages 33-34. 1306-14 [ATCC No. 53750] is a mutant of 1306-11 [ATCC No. 53263]. *See*, Examples VI, pages 35.

Claims 1, 3 and 5 of >162 are directed to biologically pure strains of *Acetobacter* with ATCC Nos. 53264 (claim 1); 53263 (claim 3); and 53524 (claim 5). Strain 53264 (claim 1) is a mutant strain of *Acetobacter* derived from strain NRRL B42. Strains 53263 (claim 3) and 53524 (claim 5) are mutant strains of *Acetobacter* derived from strain 53264 (claim 1). Therefore, if the claims are read according to alternative 1 above, then the strains of *Acetobacter* in claims 1, 3 and 5 of >162 are the same mutants as appealed claim 55.

In the alternative, claims 3-5 of >162 are directed to biologically pure strains of *Acetobacter* with ATCC Nos. 53263 (claim 3); 53250 (claim 4); and 53524 (claim 5). Strains 53263 (claim 3) and 53524 (claim 5) are mutant strains of *Acetobacter* derived from strain 53264 (claim 1). Strain 53750 (claim 4) is a mutant strain of *Acetobacter* derived from strain 53263 (claim 3). Therefore, if the claims are read according to alternative 2 above, then the strains of *Acetobacter* in claims 3-5 of >162 are mutants of strain ATCC 53264 [1306-3] and strain ATCC 53263 [1306-11].

In either interpretation of claim 55, the only difference between the claims of ≥162 and appealed claim 55 is the scope of the claim. In evaluating a double patenting rejection in circumstances such as this, we direct the examiner attention to *In re Vogel*, 422 F.2d 438, 441, 164 USPQ 619, 621 (CCPA 1970):

The first question in the analysis is: Is the same invention being claimed twice? 35 U.S.C. '101 prevents two patents from issuing on the same invention. *See, e.g., In re Boylan,* 55 CCPA 1041, 392 F.2d 1017, 157 USPQ 370 (1968). As we have said many times, Ainvention here means what is defined by the claims, whether new or old, obvious or unobvious; it must not be used in the ancient sense of Apatentable invention, or hopeless confusion will ensue. By Asame invention we mean identical subject matter. Thus the invention defined by a claim reciting Ahalogen is not the same as that defined by a claim reciting Achlorine, because the former is broader than the latter. On the other hand, claims may be differently worded and still define the same invention. Thus a claim reciting a length of Athirty-six inches defines the same invention as a claim reciting a length of Athirty-six inches defines the limitations are identical.

The claims of >162 are not identical to appealed claim 55, therefore the same invention is not being claimed twice. However, if the same invention is not being claimed twice, a second question must be asked:

Does any claim in the application define merely an obvious variation of an invention disclosed and claimed in the patent? In considering the question, the patent disclosure may not be used as prior art. *In re* Boylan, supra; In re Aldrich, 55 CCPA 1431, 398 F.2d 855, 158 USPQ 311 (1968). This does not mean that the disclosure may not be used at all. As pointed out above, in certain instances it may be used as a dictionary to learn the meaning of terms in a claim. It may also be used as required to answer the second analysis question above. We recognize that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim. A claim is a group of words defining only the boundary of the patent monopoly. It may not describe any physical thing and indeed may encompass physical things not yet dreamed of. How can it be obvious or not obvious to modify a legal boundary? The disclosure, however, sets forth at least one tangible embodiment within the claim, and it is less difficult and more meaningful to judge whether that thing has been modified in an obvious manner. It must be noted that this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined.

If the answer to the second question is no, there is no double patenting involved and no terminal disclaimer need be filed. If the answer is yes, a terminal disclaimer is required to prevent undue timewise extension of monopoly.

See, In re Vogel, 422 F.2d at 441-42, 164 USPQ at 622 (CCPA 1970):

While, using either interpretation of claim 55, the <u>strains</u> of *Acetobacter* are identical, the <u>claims</u> of >162 and claim 55 are not identical. Claim 55 is generic to the species claims of >162. AThus, the generic invention is 'anticipated' by the species of the patented invention . . . without a terminal disclaimer, the species claims preclude issuance of the generic application. *See*, *In* re *Goodman*, 11 F.3d 1046, 1053, 29 USPQ2d 2010, 2016 (Fed. Cir. 1993). Accordingly, absent a terminal disclaimer, claim 55 is properly rejected under the doctrine of obviousness-type double patenting.

Claims 49-55 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Ring or Valla or Kusakabe or Ramamurti.

Our consideration of the record leads us to conclude that this case is not in condition for a decision on appeal. Accordingly, we remand the application to the examiner to consider the following issues and to take appropriate action.

On page 4 of the Examiner's Answer, the examiner states A[t]he claims are drawn to culturing microorganisms of the genus Acetobacter and mutants thereof which are capable of producing reticulated cellulose under conditions of continuous agitation. This statement mischaracterizes the claims, which are drawn to A[a] biologically pure strain of Acetobacter claims 49-54, and A[a] mutant strain of Acetobacter, claim 55. Contrary to the examiner's characterization, none of appellants claims are Adrawn to culturing microorganisms.

At page 5 of the Examiner's Answer, the examiner states ARing, teach the production of pellicle cellulose . . . . The cellulose product is produced by culturing Acetobacter xylinum . . . . Thus, Ring [discloses] the growth of Acetobacter under conditions of agitation in order to produce cellulose fibrils intertwined and forming a pellicle, . . . which inherently comprises pellets or individual cellulose fibrils.<sup>®</sup>

At page 5 of the Examiner's Answer, the examiner states AValla, teach cellulose-negative mutants of Acetobacter xylinum, (mutants which do not produce cellulose) and the use of non-mutated microorganism for the production of cellulose products. At page 6 of the Examiner's Answer, the examiner states AValla clearly relates to the instant claims in that the use of stable strains are sought for the formation of a cellulose product and a method of making cellulose using Acetobacter is clearly disclosed. (see abstract).

At page 6 of the Examiner's Answer, the examiner states AKusakabe, teach the microbial production of a polysaccharide AX using a microorganism belonging to the genus Acetobacter. Specific culture conditions such as aeration or agitation are taught to be employed conventionally in the cultivation of microorganisms belonging to this genus (col. 2, lines 55-65)."

At page 7 of the Examiner's Answer, the examiner states ARamamurti, teach cellulose formation by Acetobacter acetigenum in a 50% (w/w) glycerol synthetic medium (see intro. on page 2267).

At page 7 of the Examiner's Answer, the examiner concludes that A[e]ach of the above cited references . . . discloses strains of Acetobacter xylinum, or Acetobacter acetigenum . . . capable of producing cellulose under conditions of agitation. Therefore, the reference strains and their use to produce cellulose is

encompassed by the claimed designated strains of <u>Acetobacter</u> and its use as herein claimed.<sup>®</sup> The examiner further concludes by stating:

However, even if the specific claimed designated strains are not identical, the reference strains would have rendered the claimed strains and the use of these strains, grown under agitation conditions to produce cellulose, obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the close relationship between strains of the same species which produce a similar or the same cellulose product under conditions of agitation.

See, Examiner's Answer, bridging paragraph, pages 7-8.

It appears that the examiner is attempting to invoke the principles of *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). When a composition is claimed in terms of a function, property or characteristic and the prior art composition is the same as the claimed composition except the function is not explicitly disclosed, the Examiner may make a rejection under both 35 U.S.C. ' 102 and ' 103, expressed as a ' 102/103 rejection. Anherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981). The examiner must provide rationale or evidence tending to show inherency. It is also incumbent upon the examiner to establish a factual basis to support the legal conclusion of obviousness when rejecting claims under 35 U.S.C. ' 103. *In re Fine*, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

Claims 49-54 are directed to A[a] biologically pure strain of *Acetobacter* and progeny thereof.<sup>®</sup>
The claimed strains of *Acetobacter* are characterized in two ways, they must:

be capable of producing substantially pure reticulated cellulose; and produce substantially low amounts of gluconic acid and ketogluconic acids in glucose-containing medium.

While the examiner focused on the production of cellulose, the examiner did not address the second characteristic of these strains, specifically, the production of substantially low amounts of gluconic acid and ketogluconic acids in glucose-containing medium. In addition, the examiners statement of the rejection does not address the requirements of claim 55, drawn to A[a] mutant strain of Acetobacter . . . . . At page 36 of their Brief, appellants state A[t]he examiner has not explained why any of the Acetobacter strains described in the cited publications possess any of the characteristic[s] possessed by the claimed strains or why it would be obvious for the person of ordinary skill in the art to produce the claimed strains. We agree with appellants. Anticipation is established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention. See, RCA Corp. v. Applied Digital Data Systems, Inc., 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir 1984).

The examiner clarifies the rejection under 35 U.S.C. 103, at page 17 of the Examiner's Answer, by stating A[h]owever, the instant claims are prima facie obvious on the basis that microorganisms are disclosed in the cited prior art which correspond to the claims, and which result in a cellulose product produced by fermentation of [an] Acetobacter under conditions of agitation. Missing from this statement is any reference to the production of substantially low amounts of gluconic acid and ketogluconic acids in glucose-containing medium.

At page 19 of the Examiner's Answer, the examiner states

Furthermore, the presence of substantially low amounts of gluconic acid and ketogluconic acids in a glucose-containing medium would have also been expected since Ring >758 discloses that rapid microbial cellulose production has been observed in a culture medium based on fructose, mannitol and sorbitol as well as in a glucose-containing medium . . . . Clearly there is no suggestion of significant amounts of gluconic acid and ketogluconic acid.

Further, one of ordinary skill in the art would have expected low amounts of these substances since cellulose is the preferred polysaccharide product and is comprised of glucose. Thus, glucose would not be available as a product for the formation of gluconic acid, or ketogluconic acid, since the glucose would be used up by the microbe to produce cellulose. Thus, low amounts of these acids would be expected.

At page 20 of the Examiner's Answer, the examiner states,

Other modifications to the claims with respect to low amounts of gluconic acid and ketogluconic acid would also have been obvious since one of skill would have known the limitations of inorganic and organic acids, and their effects on the stability of a cellulose culturing process. This feature is taught by Ring . . . wherein Ring clearly teaches the effect of HCl on pH and the importance of a neutralized pellicle.

In response to this position, appellants=state ARing *et al.* does not contain any suggestion to regulate the pH of an *Acetobacter* culture. The portion of Ring *et al.* cited by the [e]xaminer is concerned with the processing of a cellulose pellicle . . . and does not contain any discussion of regulating culture conditions.<sup>®</sup> *See*, Reply Brief, bridging paragraph of pages 8-9.

In the bridging paragraph of pages 20-21 of the Examiner's Answer, the examiner states A[s]ince specific levels of pH in fermentation are effected by the presence of acids, as exemplified by Ring, the skilled artisan would have found the regulation of acid production to be a motivational factor in maintaining a stable cell culture for the production of cellulose.®

At page 9 of the Reply Brief, appellants state Athe claimed invention is directed to strains of *Acetobacter* characterized by production of substantially low amounts of gluconic and ketogluconic acids. The [e]xaminer=s arguments appear to relate to culture conditions rather than to the claimed strains.<sup>®</sup> We agree with appellants.

Upon return of this application, the examiner should clarify the basis of the rejection. In doing so, the examiner should point to strain(s) of *Acetobacter* recognized in the prior art, and explain why the strain(s) are so similar to those claimed as to shift the burden to appellants to demonstrate a patentable difference. Keeping in mind that the initial burden of establishing unpatentability rests on the examiner, the examiner's explanation should address all the limitations found in each claim. *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). For example, for claim 49, a biologically pure strain of *Acetobacter* . . . characterized (1) as being capable of producing substantially pure reticulated cellulose, and (2) by production of substantially low amounts of gluconic acid and ketogluconic acids in glucosecontaining media.

## **OTHER ISSUES**

## **Status of the claims:**

In appellants=preliminary amendment, filed April 10, 1991 (Paper No. 2), at box 4, appellants direct the Office to cancel in this application (07/683,304) original claims 2-48 of the prior application before calculating the filing fee. Appellants state at box 12 of this preliminary amendment, filed April 10, 1991 (Paper No. 2), that AI hereby verify that the attached papers are a true copy of prior application Serial No. [07]196,496 as originally filed on May 19, 1988. Similarly, in appellants=preliminary amendment, filed April 10, 1991 (Paper No. 3), at page 2, appellants direct the Office to Acancel all claims

(claims 1-48) and add new claims.<sup>®</sup> The examiner states in the March 25, 1992 Office Action (Paper No. 6), at page 2, A[t]he receipt of the Preliminary Amendment on April 10, 1991, has been acknowledged and it has been entered. . . . In addition with respect to the claims, only claims 1-45 have been canceled and entered as such, and claims 49-55 have been added.<sup>®</sup> From this point forward there is no further discussion on the record with regards to the existence of claims 46-48, or how claims 49-55 were entered without being renumbered according to 37 C.F.R. ¹ 1.121. In addition, upon examination of the claims as they appear at pages 66-71 of the specification, claims 1-45 were never physically canceled from the application.

Adding to the confusion, the examiner indicates that claims **48**-55 are on appeal. *See*, File Wrapper's index of claims. Claim 48 does not exist in this record. In addition, page 1 of appellants=Brief indicates that A[c]laims 49-55 have been rejected. All rejections of all claims are being appealed. The Examiner's Answer confirms A[t]he statement of the status of claims contained in the brief is correct.

Upon return of the application, the examiner should take a step back to evaluate the status of the claims and then take the necessary corrective action. The examiner should notify appellants of the correct status of the claims.

# **Deposit of Biological Materials:**

Claim 55 references the following *Acetobacter* strains ATCC Nos. 53264, 53263 and 53524. There are two possible interpretations of this claim: (1) that the mutant strain is ATCC Nos. 53264, 53263 or 53524; or (2) according to appellants that the mutant strain is a mutant of ATCC Nos. 53264, 53263 or 53524. However, either interpretation, appears to make access of this material, at this location (the ATCC), necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C.

112. *See*, 37 C.F.R. 1.802(b). We recognize pages 63-65 of appellants=specification, where reference is made to the deposit of this material under the Budapest Treaty. However, missing from this reference to a deposit is an affirmative statement that hall restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent. See, 37 C.F.R.

1.808(a)(2).

Upon return of this application, the examiner should take a step back to evaluate whether a deposit requirement is necessary, and then take the necessary action. *See*, 37 C.F.R. <sup>1</sup> 1.809, *see generally*, 37 C.F.R. <sup>1</sup> 1.801-1.809.

# **Double Patenting:**

Several applications that have issued, or are currently pending, appear to be related to the application currently on appeal. Upon return of this application, the examiner should take a step back to evaluate the prosecution history of all related patents and applications, to determine whether additional double patenting issues arise.

We note United States Patent No. 5,821,109, drawn to A[a] biologically pure strain of Acetobacter. We recognize the term of this patent shall not extend beyond the expiration date of >162 discussed above. The examiner should review this file and determine if double patenting issues arise.

#### **SUMMARY**

The rejection under 35 U.S.C. ¹ 112, first paragraph, is reversed. The obviousness-type double patenting rejection is vacated in view of a new ground of rejection under 37 C.F.R. ¹ 1.196(b), and the application is remanded to the examiner for reevaluation of the 102(b)/103 rejection.

As discussed in the Time Period for Response which follows, appellant has two options with respect to the new ground of rejection, (1) have the matter reconsidered by the examiner, or (2) request that the application be reheard by the Board of Patent Appeals and Interferences upon the same record.

If appellant chooses option (1), then upon return of this application, the examiner should take into consideration any response by appellant (made within the prescribed time period for response) to the new ground of rejection under 37 C.F.R. <sup>1</sup> 1.196(b). Thereafter, the examiner should address the issues concerning the remand of this application for reevaluation of the 102(b)/103 rejection.

## TIME PERIOD FOR RESPONSE

This opinion contains a new ground of rejection pursuant to 37 C.F.R. ¹ 1.196(b) (amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 C.F.R. ¹ 1.196(b) provides that, AA new ground of rejection shall not be considered final for purposes of judicial review.@

# 37 C.F.R. 1.196(b) also provides that the appellants, <u>WITHIN TWO MONTHS FROM THE</u>

<u>DATE OF THE DECISION</u>, must exercise one of the following two options with respect to the new

ground of rejection to avoid termination of proceedings ( $^{1}$  1.197(c)) as to the rejected claims:

Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner.

Request that the application be reheard under 1.197(b) by the Board of Patent Appeals and Interferences upon the same record.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. 1.136(a).

# REVERSED-IN-PART, REMANDED-IN-PART, VACATED-IN-PART, AND 37 C.F.R. 1.196(b)

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WILLIAM F. SMITH	)
Administrative Patent Judge	)
	)
	)
	)
CAROL A. SPIEGEL	) BOARD OF PATENT
Administrative Patent Judge	) APPEALS AND
	) INTERFERENCES
	)
	)
DONALD E. ADAMS	)
Administrative Patent Judge	)

Appeal No. 1996-2123 Application No. 08/069,458

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